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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/588,558	05/25/2007	Nicolas Peter Shortis	17811US01	8274

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EXAMINER	
SPIVACK, PHYLLIS G	
ART UNIT	PAPER NUMBER
1614	
MAIL DATE	DELIVERY MODE
08/11/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/588,558	SHORTIS, NICOLAS PETER	
	Examiner	Art Unit	
	Phyllis G. Spivack	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 July 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 4-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 2, 4-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

A request for continued examination (RCE) under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after Final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office Action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 10, 2010 has been entered.

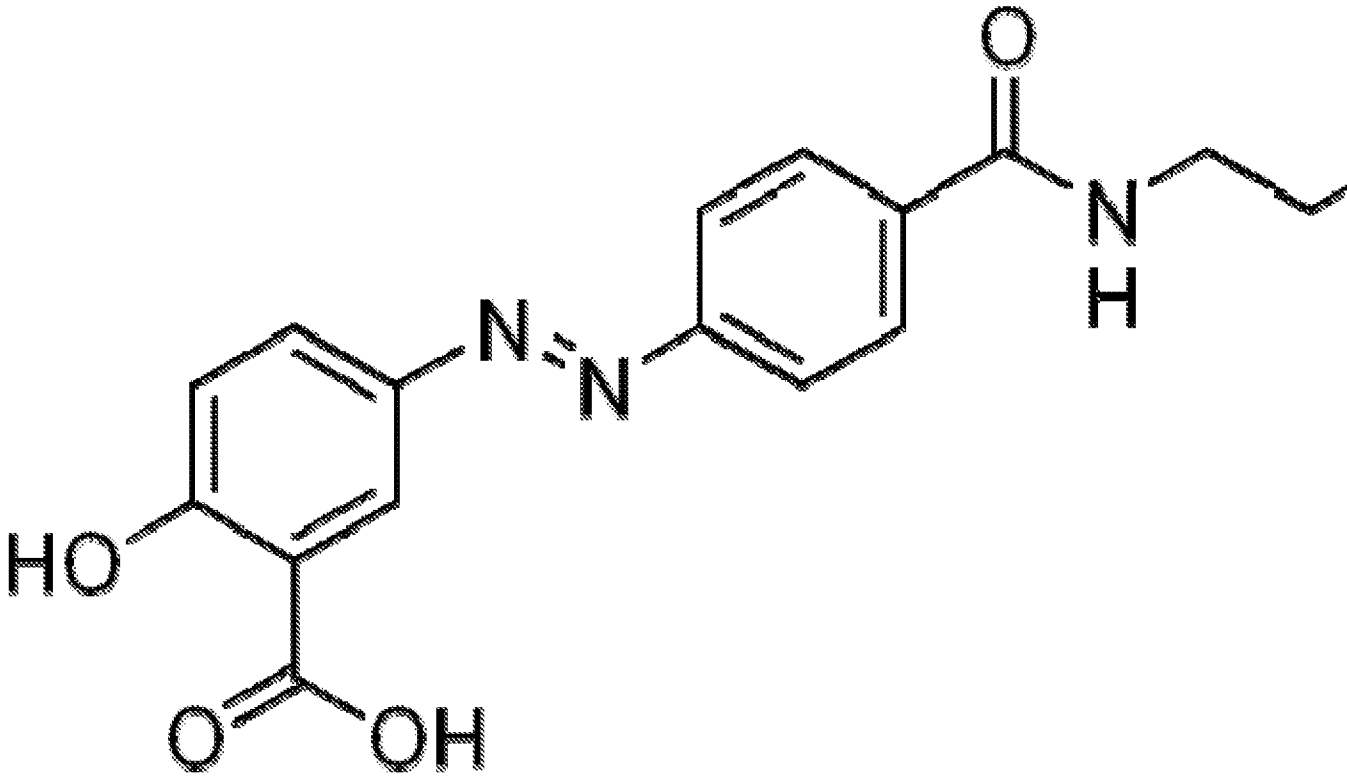
The subject matter under consideration remains those methods of treating irritable bowel syndrome comprising administering balsalazide, or a salt thereof, as well as methods drawn to administering a 4-aminosalicylic acid compound or a 5-aminosalicyclic acid compound, either of which is modified to include a 4-aminobenzoyl-β-alanine side chain, claims 1, 2 and 4-11. Those methods drawn to the treatment of conditions other than irritable bowel syndrome remain withdrawn from consideration by the Examiner, 37 CFR 1.142(b), as drawn to non-elected inventions.

Claims 1, 2 and 4-11 were rejected under 35 U.S.C. 103(a) as being unpatentable over Lin et al., U.S. Patent 6,562,629, in the last Office Action. It was asserted Lin teaches the administration of balsalazide in the treatment of irritable bowel syndrome. See column 18, lines 4-21, where 4- or 5-aminosalicylic acid compounds, and conjugated derivatives thereof, are taught to be effective antimicrobial agents in methods of treating IBS. See the Abstract. Lin teaches the co-administration of antibiotics in the treatment of IBS, as required by instant claim 10. See Example 3,

columns 24-25. Useful agents in IBS therapy include ipsalazide, sulfasalazine, olsalazine and mesalazine.

Applicant argues Lin's disclosure provides no guidance as to which compounds should be used for treating each of the various diseases, or that balsalazide offers any particular benefit over the other listed compounds. Applicant further argues balsalazide is better than the other 4-ASA and 5-ASA compounds at suppressing the symptoms of diarrhea-dominant irritable bowel syndrome due to 'inactive carrier' side chain.

Applicant's argument is not found persuasive. The rejection of record of claims 1, 2 and 4-11 under 35 U.S.C. 103(a), as being unpatentable over Lin et al., U.S. Patent 6,562,629, is maintained. Besides stating in the Abstract that a treatment of IBS is contemplated, in Example 3, column 24-25, Lin sets forth a methodology. According to Lin, the incidence of SIBO among untreated subjects suspected of having IBS is 84%, thus showing a strong association between suspected IBS and the presence of SIBO. See column 17, lines 40-50, and column 24, lines 36-40. Partial eradication of bacterial overgrowth provides a method of treatment of irritable bowel syndrome. To achieve partial eradication, an antimicrobial agent is administered. Among the antimicrobial chemotherapeutic options is balsalazide, a 5-ASA compound with an 'inactive carrier' side chain, which is depicted below. Therefore, the administration of balsalazide encompasses the limitation of claim 11, i.e., that the 4- or 5-aminosalicylic acid compound is modified to include a 4-aminobenzoyl-β-alanine side chain.



A review of the testimonial Examples on pages 10-12 of the specification fails to support an assertion of unexpected results. A comparison between balsalazide and mesalamine is mentioned only in Example 3. No dosages, dosing regimen and mode of administration are described such that unexpected results are demonstrated.

One skilled in the gastroenterology art would have been motivated to administer balsalazide with a reasonable expectation of treating IBS in a human. According to Lin, a clear association exists between SIBO and IBS. See Figures 1 and 2. Following administration, balsalazide is delivered intact to the colon where it is cleaved by bacterial azoreduction to release equimolar quantities of mesalamine, the

therapeutically active portion of the molecule, and 4-aminobenzoyl-β-alanine, an only minimally absorbed and largely inert portion of the molecule. The physical and chemical properties of balsalazide would have motivated one skilled in the gastroenterology art to select this particular antimicrobial agent.

No claim is allowed.

This is a continuation in which all claims are drawn to the same invention claimed in the earlier prosecution. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first Action. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached on 10:30 AM-7 PM.

If attempts to reach the Examiner by telephone are unsuccessful after one business day, the Examiner's supervisor, Ardin Marschel, may be reached on 591-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

August 10, 2010

/Phyllis G. Spivack/
Primary Examiner, Art Unit 1614